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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,862	12/31/2001	Hajime Nawata	Q-67472	4019

7590 02/09/2004

SUGHRUE MION, PLLC
2100 Pennsylvania Avenue, NW
Washington, DC 20037-3213

EXAMINER

WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,862	NAWATA ET AL.	
	Examiner	Art Unit	
	Jon P Weber, Ph.D.	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 Dec 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 04/19/02.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Status of the Claims

Claims 1-6 have been presented for examination.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-6 in the Paper filed 26 November 2003 is acknowledged. Non-elected claims 7-14 have been canceled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to and claims 1-6 rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, failing to provide an enabling disclosure and failing to present the best mode contemplated by applicant for carrying out the invention without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological material.

It is apparent that the microorganism(s), KGN cells, is/are required to practice the claimed invention. As a required element it/they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it/they is/are not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the microorganism(s). See 37 C.F.R. § 1.802.

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The specification does not provide a repeatable process for obtaining the microorganism(s) and it is not apparent if the microorganism(s) is/are readily available to the public. **The specification must contain the date that the microorganism(s) was/were deposited, the name of the microorganism(s) and the address of where the microorganism(s) was/were deposited.**

If the deposit(s) has/have been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or record over his/her signature, and registration number, stating that the specific strain(s) has/have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

If the deposit(s) has/have not been made under the Budapest Treaty, then in order to certify that the deposit(s) meets the criteria set forth in 37 C.F.R. § 1.801-1.809, Applicant(s) may provide assurance of compliance by an affidavit or declaration, or by a statement by an Attorney of record over his/her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit(s) will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

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(d) a viability statement in accordance with the provisions of 37 C.F.R. § 1.807; and
(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

The cells do not appear to have been deposited under Budapest and are not freely available, inasmuch as they are available only under restriction "b".

In addition, the identifying information set forth in 37 C.F.R. § 1.809 (d) should be added to the specification. See 37 C.F.R. § 1.803-1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Saitoh et al. (23 Nov 2001).

Saitoh et al. (23 Nov 2001) disclose testing for changes in aromatase activity in KGN cells with tributyltin and triphenyltin. Aromatase activity was detected by [³H]H₂O release upon conversion of [1β-³H]androstenedione (A) to estrone (E1). The aromatase activity was confirmed by measuring estradiol content by RIA. The KGN cells are identical to the instantly claimed cells.

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Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Nishi et al. (Jan 2001).

Nishi et al. (Jan 2001) disclose that the aromatase activity of KGN cells is stimulated by (Bu)₂cAMP or FSH. Aromatase activity was detected by [³H]H₂O release upon conversion of [1β-³H]androstenedione (A) to estrone (E1). The aromatase activity was confirmed by measuring estradiol content by RIA. The KGN cells are identical to the instantly claimed cells.

Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Mu et al. (Jan 2001).

Mu et al. (Jan 2001) disclose that the aromatase activity of human granulosa cells is inhibited by Troglitizone (TGZ) and the RXR specific ligand LG100268 (LG). Aromatase activity was detected by [³H]H₂O release upon conversion of [1β-³H]androstenedione (A) to estrone (E1). The aromatase activity was confirmed by measuring estradiol content by RIA. The human granulosa cells appear to be identical to the instantly claimed cells.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Mu et al. (2000).

Mu et al. (2000) disclose that the aromatase activity of human granulosa cells is inhibited by Troglitizone (Tro) and the RXR specific ligand LG100268 (LG). Aromatase activity was detected by [³H]H₂O release upon conversion of [1β-³H]androstenedione (A) to estrone (E1). The aromatase activity was confirmed by measuring estradiol content by RIA. The human granulosa cells appear to be identical to the instantly claimed cells.

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Claims 1-2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Nawata et al. (1995).

Nawata et al. (1995) disclose that the activity of aromatase in human osteoblast-like cells is stimulated by dexamethasone and $1\alpha,25$ -dihydroxyvitamin D.

Claim 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Zacharewski (1998).

Zacharewski (1998) discloses that it was previously shown that aromatase activity could be inhibited in porcine granulosa cells by 4-hydroxyandrostendione, aminoglutethimide phosphate and ketoconazole.

Claim 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Mak et al. (1999).

Mak et al. (1999) disclose a yeast screen system for aromatase inhibitors and ligands for androgen receptor. Aromatase activity was detected by [^3H]H₂O release upon conversion of [1β - ^3H]androstenedione (A) to estrone (E1).

Claims 1-2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitawaki et al. (1993) or Chen et al. (1999).

Kitawaki et al. (1993) and Chen et al. (1999) both disclose using MCF-7 human breast cancer cells to screen for inhibitors of aromatase. Aromatase activity is measured by the tritiated water method.

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Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Powlin et al. (1998).

Powlin et al. (1998) disclose screening for aromatase inhibitors with testis and ovary explants. This system was of only limited utility for the desired screening with known inhibitors.

Claims 1-2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanaka et al. (1993).

Tanaka et al. (1993) disclose activating aromatase activity in human osteoblast-like osteosarcoma cells with dexamethazone and other glucocorticoids.

Other references cited by examiner but not relied upon are cited to establish the state of the art.

Stresser et al. (2000) disclose high-throughput screening for aromatase inhibitors with purified recombinantly produced (baculovirus/insect cell) aromatase using a fluorometric substrate.

Okubo et al. (Feb 2001) disclose inhibiting aromatase expression using MDA-MB-231 human breast cancer cell line.

Yang et al. (1999) disclose inhibiting aromatase expression using HepG2 cell line with taxophene.

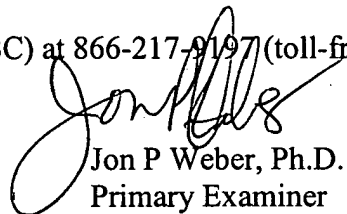
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 571-272-0925.

The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
5 February 2004